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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,994	12/03/2003	Rakha Hari Das	41144F010	5203
441	7590	08/19/2008	EXAMINER	
SMITH, GAMBRELL & RUSSELL 1130 CONNECTICUT AVENUE, N.W., SUITE 1130 WASHINGTON, DC 20036			SWARTZ, RODNEY P	
ART UNIT	PAPER NUMBER			
			1645	
MAIL DATE	DELIVERY MODE			
			08/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/725,994	<b>Applicant(s)</b> DAS ET AL.
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12February2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7,9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7,9 and 11-19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/1648)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' Response to Notice of Noncompliant Amendment, received 9 May 2008, is acknowledged.
2. Applicants' Response to Office Action, received 12 February 2008, is acknowledged. Claims 1, 2, 4, 5, 7, 9, 11, 12, 13, 16, 17, and 19 have been amended. Claims 8 and 10 have been canceled.
3. Claims 1-7, 9, and 11-19 are pending and under consideration.

**Rejections/Objections Withdrawn/Moot**

4. The rejection of claims 8 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancelation of the claims.
5. The objection to Figure 2 for not containing a sequence identifier number is withdrawn in light of the amendment of the specification.
6. The objection to Figure 3 is withdrawn in light of the substitute figure.

The objection to claim 1 is withdrawn in light of the amendment of the claim

7. The objection to claim 4 is withdrawn in light of the amendment of the claim.
8. The objection to claim 7 is withdrawn in light of the amendment of the claim.
9. The objection to claim 16 is withdrawn in light of the amendment of the claim.
10. The rejection of claims 4 and 5 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in light of applicants' statement that the range is referring to the total mix.

**Rejections Maintained**

11. The rejection of claims 1-7, 9, 11-16 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite for "clarifying the clinical specimens from containment", is maintained.

Applicants argue that the specification clarifies the meaning of this phrase.

The examiner has considered applicants' argument, but does not find it persuasive. The cited pages 10, 12, 13, and 18 of the specification do not define what this phrase means.

12. The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite, is maintained.

Applicants argue that the Markush language should be interpreted conventionally.

The examiner has considered applicants' argument, but does not find it persuasive because it remains unclear whether one, two or more primers are included.

13. The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite, is maintained.

Applicants argue that the Markush language should be interpreted broadly.

The examiner has considered applicants' argument, but does not find it persuasive because it remains unclear whether one, two or more primers are included.

### **Conclusion**

14. All claims are finally rejected.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisors, Shannon Foley (571)272-0898, and Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 3, 2008

<b>Application Number</b> 	<b>Application/Control No.</b>	<b>Applicant(s)/Patent under Reexamination</b>
	10/725,994	DAS ET AL.
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645